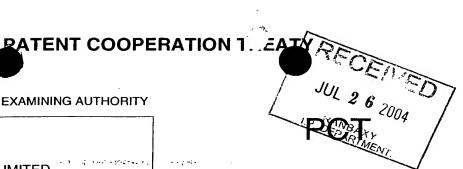


From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

194 - 1944)

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY **EXAMINATION REPORT** 

(PCT Rule 71.1)

Date of mailing

(day/month/year)

19.07.2004

Priority date (day/month/year)

Applicant's or agent's file reference

RLL-265WO

IMPORTANT NOTIFICATION

International application No.

PCT/IB 03/02166 06.06.2003 07.06.2002

Applicant

RANBAXY LABORATORIES LIMITED et al.

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

International filing date (day/month/year)

Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article . 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

**European Patent Office** D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465

**Authorized Officer** 

Ruiz Fernandez, J

Tel. +49 89 2399-7960





## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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(PCT Article 36 and Rule 70)

and the Walter transfer and the contract of th

Applican		ent's file reference	FOR FURTHER A	CTION		n of Transmittal of International ramination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/02166			International filing date 06.06.2003	(day/mont	· · · · · · · · · · · · · · · · · · ·	Priority date (day/month/year) 07.06.2002
Internation A61K9		ent Classification (IPC) or b	oth national classification	and IPC		
Applican		ABORATORIES LIMIT	ED et al.			. 1817
1. Th	nis inter uthority	national preliminary exa and is transmitted to the	mination report has be applicant according to	en prepar Article 30	ed by this Inte 3.	rnational Preliminary Examining
2. Th	nis REP	ORT consists of a total of	of 6 sheets, including t	his cover	sheet.	•
	bee	s report is also accompa n amended and are the e Rule 70.16 and Section	basis for this report an	d/or sheet	s containing re	on, claims and/or drawings which have ectifications made before this Authority he PCT).
Th	iese an	nexes consist of a total of	of sheets.			,
3. Th	3. This report contains indications relating to the following items:					The setting of the second of t
1	$\boxtimes$	Basis of the opinion				
11						
III ☑ Non-establishment of opinion with regard to novelty, inventive step and indus IV ☐ Lack of unity of invention			nd industrial applicability			
V	_				ventive step or industrial applicability;	
VI		Certain documents cite	ed			
VII		Certain defects in the i	nternational applicatior	า		
VII	VIII   Certain observations on the international application					
Date of su	ubmissio	on of the demand		Date of c	completion of thi	s report
06.01.2	06.01.2004			19.07.2004		
Name and mailing address of the international preliminary examining authority:			Authorized Officer			
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465			Hedegaard, A Telephone No. +49 89 2399-8644			

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

and the same

PCT/IB 03/02166

I.	Bas	is o	f the	report

1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	De	Description, Pages						
	1-1	7	as originally filed					
	Cla	nims, Numbers						
		·						
	1-5	3	as originally filed					
2.	Wit lan	With regard to the <b>language</b> , all the elements marked above were available or furnished to this Authority in the anguage in which the international application was filed, unless otherwise indicated under this item.						
	The	These elements were available or furnished to this Authority in the following language: , which is:						
		$\Box$ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b						
		the language of pub	lication of the international application (under Rule 48.3(b)).					
		the language of a tra Rule 55.2 and/or 55.	anslation furnished for the purposes of international preliminary examination (under 3).					
3.	Wit inte	h regard to any <b>nucle</b> rnational preliminary	eotide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:					
		contained in the inte	rnational application in written form.					
		filed together with th	e international application in computer readable form.					
		furnished subsequer	ntly to this Authority in written form.					
		furnished subsequently to this Authority in computer readable form.						
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.						
		The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.						
4.	The	amendments have re	esulted in the cancellation of:					
٠.		the description,	pages:					
		the claims,	Nos.:					
		the drawings,	sheets:					
5.		This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).						
	(Any replacement sheet containing such amendments must be referred to under item 1 and annexor report.)							
6.	Add	itional observations, i	f necessary:					

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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Ш	. No	n-establishment of opinion v	vith re	gard to nov	elty, inventive step and industrial applicability	
1.	The obv	The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:				
		□ the entire international application,				
	$\boxtimes$	claims Nos. 49-53			·	
		because:				
	the said international application, or the said claims Nos. relate to the following subject matter which do not require an international preliminary examination (specify):					
	see separate sheet					
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so uncleathat no meaningful opinion could be formed (specify):					
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opin could be formed.				ely supported by the description that no meaningful opinion	
		no international search report	has b	een establisl	ned for the said claims Nos.	
2.	or a	A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative anstructions:				
		the written form has not been	furnisl	ned or does	not comply with the Standard.	
		the computer readable form h	as not	been furnish	ned or does not comply with the Standard.	
۷.	Rea cita	easoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; tations and explanations supporting such statement				
1.	Stat	Statement				
		velty (N)		Claims Claims	47,48 1-46,49-53	
		ventive step (IS)		Claims Claims	1-53	
	Indu	strial applicability (IA)	Yes: No:	Claims Claims	1-48	

2. Citations and explanations

see separate sheet

#### Re Section III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 49-53 relate to subject-matter considered by this Authority to be covered 1. by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

### Re Section V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO-A-0076478

D2: WO-A-0059477

D3: WO-A-0151033

D4: EP-A-0 284 849

D5: WO-A-03002151

D6: WO-A-03035040

D1 discloses (see claim 1 and example 5) controlled release tablets comprising gabapentin and a rate-controlling polymer such as HPMC. A dissolution profile wherein after 5 hours no more than 80% of active ingredient is released is shown for a similar tablet comprising 5-aminosalicylic acid (example 1). The tablets are made by granulation of active ingredient in an inert matrix.

D2 discloses (see p. 5, l. 5-36; p. 7, l. 21; and p. 11, l. 19 - p. 12, l. 7) controlled release tablets comprising e.g. gabapentin and a rate-controlling polymer such as HPMC.

D3 discloses (see claims 1, 2 and 8) controlled release tablets comprising an active ingredient, e.g. gabapentin, and a matrix, e.g. a hydrophilic matrix, said tablets being obtained by granulation and compression.

2. Claims 1-3, 27-29 and 49 do not meet the requirements of Article 6 PCT in that

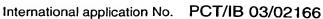
### INTERNATIONAL PRELIMINARY **EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/02166

the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved (a certain release profile) which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should be added.

- 3. The subject-matter of independent claims 1 and 49 is not novel (Art. 33(2) PCT) over D1-D3, each document taken separately (see above under item 1). As mentioned above under item 2 the feature "therapeutically effective plasma levels of gabapentin for a period of up to about 12 hours" is not suitable for making a clear distinction over the prior art.
- 4. The subject-matter of independent claim 27 is not novel over D3 (see above under item 1).
- 5. The subject-matter of independent claims 47 and 48 is novel since the exact process features have not been disclosed in the prior art documents.
  - The subject-matter of said claims differs from D1-D3 in specifying that the gabapentin is granulated with 5% to 80% by weight of HPMC/HPC having a certain viscosity. However, it is well known to the skilled person to granulate active ingredients with HPMC in order to obtain prolonged release of the therapeutic agent within a period of up to 12 hours. (see e.g. D4, p. 5, I. 19-35). Hence, the subject-matter of said claims does not appear to involve an inventive step (Art. 33(3) PCT).
- 6. A positive international preliminary report for the subject-matter of the dependent claims 2-26, 28-46 and 50-53 can only be established when they refer to independent claims which meet the requirements of the PCT.
- For the assessment of the present claims 49-53 on the question whether they are 7. industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of





**EXAMINATION REPORT - SEPARATE SHEET** 

the second in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

#### 8. Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-03002151	09.01.2003	19.06.2002	26.06.2001
WO-A-03035040	01.05.2003	25.10.2002	25.10.2001

Although WO-A-03002151 (D5) and WO-A-03035040 (D6) do not constitute prior art within the meaning of Rule 64.1(b) PCT, they could become of relevance in the regional phase.

No check has been made as to whether the priorities have been validly claimed.